



Printing date 19.07.2024 Version number 2 (replaces version 1) Revision: 19.07.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: EXAFLEX PUTTY Catalyst
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxillary for dental technology
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00

Fax +32/(0)16/40.26.84 msds@gc.dental

- · Further information obtainable from: Regulatory affairs
- · 1.4 Emergency telephone number:

International: +01-813-248-0585 (ChemTel Inc.)

National poison center for United Kingdom of Great Britain and Northern Ireland:

Belfast: +44 28 90 63 2032 Birmingham: +44 121 507 4123 Edinburgh: +44 131 242 1383

Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180

Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

· Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms



· Signal word Danger

· Hazard-determining components of labelling: Quartz

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· Hazard statements

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous components:						
CAS: 14808-60-7 EINECS: 238-878-4		STOT RE 1, H372 substance with a Community workplace exposure limit	50-<75%			
CAS: 8012-95-1 EINECS: 232-384-2	Paraffin oils	Asp. Tox. 1, H304; Aquatic Chronic 4, H413	5-<10%			

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: If symptoms persist consult doctor.
- · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

- · After skin contact: If skin irritation continues, consult a doctor.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

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· For safety reasons unsuitable extinguishing agents: Water with full jet

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid formation of dust.

Wear protective clothing.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Prevent formation of dust.

Dispose of the material collected according to regulations.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

- · Information about fire and explosion protection: Dust can combine with air to form an explosive mixture.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
- · Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

14808-60-7 Quartz

WEL Long-term value: 0.1* mg/m³

respirable

· Additional information: The lists valid during the making were used as basis.

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- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Do not inhale dust / smoke / mist.

Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed.

- · Respiratory protection: Suitable respiratory protective device recommended.
- · Hand protection Protective gloves
- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eve/face protection Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Solid · Colour: Blue · Odour: **Odourless** · Odour threshold: Not determined. Melting point/freezing point: Undetermined. · Boiling point or initial boiling point and boiling range Undetermined. · Flammability Not determined.

· Lower and upper explosion limit

· Lower: Not determined. Not determined. · Upper: · Flash point: *Not applicable.* Undetermined. · Auto-ignition temperature: · Decomposition temperature: Not determined. Not applicable. $\cdot pH$

· Viscosity:

· Kinematic viscosity *Not applicable.* · Dynamic: Not applicable.

· Solubility

Insoluble. · water: · Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure:

Not applicable. · Density and/or relative density

· Density: Not determined. · Relative density Not determined. · Vapour density Not applicable.

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· Appearance:

· Form: Pasty

Important information on protection of health and environment, and on safety.

• Ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

· Change in condition

• Evaporation rate Not applicable.

· Information with regard to physical hazard classes

Void · Explosives · Flammable gases Void Void · Aerosols Void · Oxidising gases · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability

· Desensitised explosives

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Void

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification: No further relevant information available.
- · STOT-repeated exposure

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.

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- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 No further relevant information available.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information				
· 14.1 UN number or ID number				
· ADR, ADN, IMDG, IATA	not regulated			
· 14.2 UN proper shipping name				
· ADR, ADN, IMDG, IATA	not regulated			
· 14.3 Transport hazard class(es)				
· ADR, ADN, IMDG, IATA				
· Class	not regulated			
· 14.4 Packing group	1 , 1			
· ADR, IMDG, IATA	not regulated			
		•		
· 14.5 Environmental hazards:				

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· 14.6 Special precautions for user	Not applicable.		
· 14.7 Maritime transport in bulk according to IMO instruments Not applicable.			
· UN "Model Regulation":	not regulated		

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Poisons Act
- · Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H304 May be fatal if swallowed and enters airways.

H372 Causes damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Asp. Tox. 1: Aspiration hazard - Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4

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- ·Sources
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- * * Data compared to the previous version altered.

This version replaces all previous versions.

Disclaimer:

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